

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 1998

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 1-9898  
**ORGANOGENESIS INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE 04-2871690  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION) (I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

150 DAN ROAD, CANTON, MA 02021  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (781) 575-0775

Indicate by check mark whether the registrant (1) has filed all reports required to be filed bY Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES (X) NO ( )

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at November 3, 1998 was 29,590,640 shares (excluding treasury shares).

## ORGANOGENESIS INC.

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\* No information provided due to inapplicability of item

**PART I - FINANCIAL INFORMATION**  
**ITEM 1 - FINANCIAL STATEMENTS**

**ORGANOGENESIS INC.**

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

	September 30, 1998	December 31, 1997
(unaudited)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$9,360	\$333
Investments	14,424	5,812
Inventory	707	488
Other current assets	<u>742</u>	<u>439</u>
	25,233	7,072
Property and equipment -		
Less accumulated depreciation of \$8,942 and \$7,865	6,530	6,615
Other assets	<u>93</u>	<u>93</u>
	<u><u>\$31,856</u></u>	<u><u>\$13,780</u></u>
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$465	\$643
Accrued expenses	<u>2,259</u>	<u>1,586</u>
	2,724	2,229
Deferred rent payable	-	28
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, par value \$1.00; authorized 1,000,000 shares:		
Series C Convertible Preferred; designated 200 shares;		
140 shares issued and outstanding as of September 30, 1998		
Common stock, par value \$.01; authorized 40,000,000 shares:		
issued and outstanding 29,629,770 and 28,950,400 shares as		
of September 30, 1998 and December 31, 1997, respectively	296	290
Additional paid-in capital	124,311	98,219
Accumulated deficit	(95,228)	(86,986)
Treasury stock at cost, 25,000 shares at September 30, 1998	<u>(247)</u>	-
Total stockholders' equity	<u><u>29,132</u></u>	<u><u>11,523</u></u>
	<u><u>\$31,856</u></u>	<u><u>\$13,780</u></u>

The accompanying notes are an integral part of the consolidated financial statements.

## ORGANOGENESIS INC.

**CONSOLIDATED STATEMENTS OF OPERATIONS AND  
OF COMPREHENSIVE OPERATIONS**  
(Unaudited, in thousands, except share data)

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,	
	<u>1998</u>	<u>1997</u>	<u>1998</u>
	<u>1998</u>	<u>1997</u>	<u>1997</u>
<b>Revenues:</b>			
Research and development support from related party	\$-	\$-	\$6,750
Product sales to related party, royalties and other income	352	144	854
Interest income	<u>392</u>	<u>125</u>	<u>785</u>
Total revenues	<u>744</u>	<u>269</u>	<u>8,389</u>
<b>Costs and expenses:</b>			
Research and development	4,913	3,827	12,698
General and administrative	1,521	895	3,933
Non-cash charge for stock option extension	=	=	<u>5,555</u>
Total costs and expenses	<u>6,434</u>	<u>4,722</u>	<u>16,631</u>
Net loss	<u><u>\$(5,690)</u></u>	<u><u>\$(4,453)</u></u>	<u><u>\$(8,242)</u></u>
Net loss per common share-basic and diluted	<u><u>\$(.19)</u></u>	<u><u>\$(.16)</u></u>	<u><u>\$(.28)</u></u>
Weighted average number of common shares outstanding	<u><u>29,521,312</u></u>	<u><u>28,443,188</u></u>	<u><u>29,255,956</u></u>
<b>CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS</b>			
Net loss	\$(5,690)	\$(4,453)	\$(8,242)
Other comprehensive income (loss)	=	=	=
Comprehensive net loss	<u><u>\$(5,690)</u></u>	<u><u>\$(4,453)</u></u>	<u><u>\$(8,242)</u></u>
	<u><u><u>\$(5,690)</u></u></u>	<u><u><u>\$(4,453)</u></u></u>	<u><u><u>\$(8,242)</u></u></u>

The accompanying notes are an integral part of the consolidated financial  
statements.

## ORGANOGENESIS INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

For the  
Nine Months  
Ended September 30,

	<u>1998</u>	<u>1997</u>
Cash flows from operating activities:		
Net loss	\$(8,242)	\$(15,113)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,077	1,215
Issuance of stock options	-	50
Non-cash charge for stock option extension	-	5,555
Changes in assets and liabilities:		
Inventory	(219)	(130)
Other current assets	(303)	(338)
Other assets	-	(3)
Accounts payable	(178)	(863)
Accrued expenses	673	(1,450)
Deferred rent payable	<u>(28)</u>	<u>(32)</u>
Cash used in operating activities	<u>(7,220)</u>	<u>(11,109)</u>
Cash flows from investing activities:		
Capital expenditures	(992)	(826)
Purchase of investments	(15,224)	(5,000)
Sales/maturities of investments	<u>6,612</u>	<u>10,200</u>
Cash provided by (used in) investing activities	<u>(9,604)</u>	<u>4,374</u>
Cash flows from financing activities:		
Proceeds from sale of preferred stock, net	19,117	-
Proceeds from sale of common stock	6,000	-
Proceeds from exercise of warrants	-	4,571
Proceeds from exercise of stock options	981	1,907
Purchase of treasury stock	<u>(247)</u>	-
Cash provided by financing activities	<u>25,851</u>	<u>6,478</u>
Increase in cash and cash equivalents	9,027	(257)
Cash and cash equivalents, beginning of period	<u>333</u>	<u>399</u>
Cash and cash equivalents, end of period	<u><b>\$9,360</b></u>	<u><b>\$142</b></u>

The accompanying notes are an integral part of the consolidated financial  
statements.

## ORGANOGENESIS INC.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(Unaudited)

This Form 10-Q and other public filings or statements made by the Company from time to time which concern the Company's business outlook; future financial performance; anticipated profitability, revenues, expenses or capital expenditures; future funding under collaborative agreements; future clinical or regulatory events; and statements concerning expectations as to any future events, as well as other statements which are not historical fact, are forward- looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in these forward- looking statements. Factors that might cause such a difference include, but are not limited to, those discussed under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Additional Cautionary Considerations" sections in this report and included in publicly available filings with the Securities and Exchange Commission, such as the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

**1. Basis of Presentation:**

The accompanying unaudited consolidated financial statements of Organogenesis Inc. (the "Company"), have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the nine months ended September 30, 1998 are not necessarily indicative of the results to be expected for the year ending December 31, 1998.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 1997 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

2. New Accounting Pronouncement:

In June 1997, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"). SFAS 130 requires that changes in comprehensive income be shown in a financial statement that is displayed with the same prominence as other financial statements. This Statement also requires that an entity classify items of other comprehensive income by their nature. For example, other comprehensive income may include, but are not limited to, foreign currency translation adjustments, minimum pension liability adjustments, and unrealized gains and losses on marketable securities classified as available-for-sale. SFAS 130 is effective for fiscal years beginning after December 15, 1997 and, accordingly, was adopted during the first quarter of 1998. The disclosure provisions of SFAS 130 are not material to the Company's current consolidated financial presentation; however, SFAS 130 may materially affect future financial statement presentations.

3. Revenue Recognition:

Research and development support revenue under the collaborative agreement with Novartis Pharma AG ("Novartis" or "related party") is recognized as related expenses are incurred or contractual obligations are met. Revenue from Apligraf\* sales is recognized upon shipment or, in certain cases, after fulfillment of firm purchase orders in accordance with the Manufacturing and Supply Agreement between the Company and Novartis. Any related royalty revenue is recognized when net sales are reported to the Company by Novartis. Other product revenues are recognized upon shipment. Other royalty revenue is recorded as earned. Deferred revenue arises from the difference between cash received and revenue recognized in accordance with these policies.

4. Inventory:

Inventory is stated at the lower of cost or market, cost being determined using the first-in, first-out method of accounting. Inventory consisted of the following (in thousands):

	September 30, <u>1998</u>	December 31, <u>1997</u>
(unaudited)		
Raw Materials	\$407	\$286
Work in Process	288	197
Finished Goods	<u>12</u>	<u>5</u>
	<u><u>\$707</u></u>	<u><u>\$488</u></u>

5. Other Current Assets:

Included in other current assets at September 30, 1998 and December 31, 1997 is a receivable due from Novartis of approximately \$379,000 and \$190,000, respectively.

\* Apligraf is a registered trademark of Novartis.

6. Collaborative Agreements:

In January 1996, the Company and Novartis entered into an agreement granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, Novartis is responsible for Apligraf sales and marketing costs worldwide, as well as all clinical trials, registrations and patent costs outside the U.S. The Company supplies Novartis' global requirements for Apligraf and receives both a per unit manufacturing payment and royalty revenues on product sales. Novartis has agreed to provide the Company up to \$40,000,000 in equity investments, research support and milestone payments, an increase of \$2,500,000 from prior year due to the addition of a research and development support milestone. The Company received \$12,750,000 from Novartis during the first nine months of 1998. Of this amount, \$6,750,000 represents research and development milestone payments and \$6,000,000 represents milestone equity investments. To date, Novartis has funded \$26,750,000 of the \$40,000,000 under the agreement. The remaining payments will be received based upon achievement of specified events.

7. Preferred Stock:

In March 1998, the Company completed a placement of 200 shares of Series C Convertible Preferred Stock ("Series C Preferred Stock") and warrant financing with two institutional investors at a price of \$100,000 per share. Proceeds from the offering, net of placement agent fees and expenses, were approximately \$19,117,000. The Series C Preferred Stock pay no dividends, have no voting rights and are convertible into Common Stock on a scheduled basis over the next two years based on market price at time of conversion (up to \$28.80 per share). The Company may call for conversion of all or part of the shares of Series C Preferred Stock under certain conditions based on continued improvement in the price of the Company's Common Stock. Conversions by the investors are subject to certain limits; no limits exist for conversions on redemption or upon a major transaction. Mandatory conversion is March 26, 2000, at which time the Company has the option to redeem any outstanding Series C Preferred Stock in cash or by issuing Common Stock. In addition, the investors received three-year warrants to purchase an aggregate of 200,000 shares of Common Stock at \$31.20 per share. The warrants may be exercised at any time prior to April 2001. Related to this placement, the Company issued a warrant to purchase an aggregate of 50,000 shares of Common Stock at \$28.80 per share to the placement agent, which expires March 25, 2001. The total fair value of all warrants was estimated to be approximately \$2,509,000 and is included in additional paid-in capital.

In April 1998, the Company filed a registration statement for 1,800,000 shares of Common Stock, which is the maximum number of shares that may be acquired relating to this transaction. All shares have been reserved for issuance. The Securities and Exchange Commission declared this registration statement effective on May 5, 1998.

In May and September 1998, an aggregate of \$6,000,000 face amount of the Series C Preferred Stock issued in March 1998 was converted into Common Stock resulting in the issuance of approximately 293,000 shares of Common Stock. This conversion was a non-cash transaction.

In July 1998, the investors exercised their right to receive additional warrants to purchase 150,000 shares of Common Stock at \$17.45 per share with an expiration date of March 26, 2001. No further warrants may be issued under the Series C Preferred Stock placement.

8. Common Stock:

The Company received \$6,000,000 from Novartis during the nine months ended September 30, 1998, which represents milestone equity investments for approximately 240,000 shares of Common Stock. As a result of these equity investments and a prior equity investment made in January 1996, Novartis holds 2.2% of the outstanding shares of the Company as of September 1998.

On April 15, 1998, the Board of Directors declared a one for four stock split in the form of a stock dividend for stockholders of record on April 22, 1998. The stock dividend was payable on April 29, 1998 and resulted in the issuance of approximately 5,826,000 additional shares of Common Stock. All related data in the consolidated financial statements and notes herein are restated to reflect the stock dividend for all periods presented.

9. Treasury Stock:

On September 1, 1998, the Company announced that its Board of Directors had authorized it to repurchase, from time to time through open-market transactions, up to 500,000 shares of the Company's Common Stock. As of September 30, 1998, the Company had repurchased 25,000 shares of the Company's Common Stock, for an aggregate purchase price of approximately \$247,000. The repurchase program continues in the fourth quarter.

10. Earnings per Share:

Net loss per common share basic and diluted for the three months and nine months ended September 30, 1998, is based on the weighted average number of common shares outstanding during the periods. Potentially dilutive securities include stock options, warrants and convertible preferred stock, however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive.

## ORGANOGENESIS INC.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**Overview:

Organogenesis Inc. (the "Company") designs, develops and manufactures medical therapeutics containing living cells and/or natural connective tissue. The Company was formed to advance and apply tissue engineering to major medical needs. The Company's product development focus includes living tissue replacements, cell-based organ assist devices and other tissue-engineered products.

On May 22, 1998, the Company's lead product, Apligraf\*, was approved for the treatment of venous leg ulcers by the U.S. Food and Drug Administration ("FDA"). Apligraf is the only manufactured product containing living human cells to be approved for marketing in the United States. Novartis Pharmaceuticals Corporation launched Apligraf in the United States in June 1998. Novartis Pharma AG has global Apligraf marketing rights and also markets Apligraf in Canada.

Novartis' marketing strategy is to first establish Apligraf as the new standard of care for venous leg ulcers. The next large market for Apligraf is expected to be diabetic ulcers. Enrollment in the Apligraf diabetic ulcer pivotal trial is anticipated to be completed in 1998. The Company expects to begin the FDA registration process for Apligraf in diabetic ulcers in the second half of 1999. An Apligraf study in burns has been completed, and the Company plans to publish the data. Two studies in skin surgery have been completed, and their data has been or is expected to be published. A large, controlled Apligraf trial studying the cosmetic outcome of wounds due to skin cancer removal is underway. The Company also plans to initiate a trial in pressure sores within the next few months. There can be no assurances that Apligraf trials currently underway or planned will yield favorable results, that an Apligraf PMA supplement for use in diabetic ulcers will be submitted in 1999, or that any Apligraf regulatory submissions will be approved in a timely manner, if at all.

The Company expects a gradual ramp-up in sales during the remainder of 1998, into 1999. The Company expects production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. There can be no assurance that the Company will realize sufficient production volume or otherwise reduce its production costs to significantly improve gross margins. The Company is dependent on Novartis for the successful marketing of Apligraf. There can be no assurance that Novartis will succeed with registrations and marketing of Apligraf or that the Company will be able to meet the production demand of global commercialization.

The Company has an active business development program related to products and technologies in its pipeline. Among the products for which the Company is seeking a partner is GraftPatch(TM), which has been cleared for marketing in the United States under the FDA's Section 510(k) notification process. No assurance can be given that the Company will be able to identify and/or reach agreement with an appropriate partner in a timely manner.

Results of Operations may vary significantly from quarter to quarter depending on, among other factors, the progress of the Company's research and development efforts, the receipt of milestone and research and development support payments, if any, from Novartis, product revenues, manufacturing costs, the timing of certain expenses and the establishment of additional collaborative agreements, if any.

\* Apligraf is a registered trademark of Novartis.

Results of Operations:

## Revenues

Total revenues were \$744,000 and \$8,389,000 for the three and nine months ended September 30, 1998, compared to \$269,000 and \$3,338,000, for the same periods in 1997. Product sales to related party, royalties and other income increased to \$352,000 and \$854,000 for the three and nine months ended September 30, 1998, compared to \$144,000 and \$444,000, for the same periods in 1997 due to increased supply of product to Novartis. Revenues for the nine months ended September 30, 1998, include recognition of \$6,750,000 for research and development milestones received under the collaborative agreement with Novartis (See "Notes to Consolidated Financial Statements") versus \$2,500,000 in support for the same period in 1997. Interest income increased to \$392,000 and \$785,000 for the three and nine months ended September 30, 1998, compared to \$125,000 and \$394,000 for the same periods in 1997, primarily due to the increase in funds available for investment.

## Costs and Expenses

Research and development expenses increased to \$4,913,000 and \$12,698,000 for the three and nine months ended September 30, 1998, compared to \$3,827,000 and \$10,096,000, for the same periods in 1997. The increase was primarily due to clinical trials activity, including the Apligraf diabetic ulcer pivotal trial and non-recurring expenses related to FDA approval, progressing preclinical programs, including the Vitrix dermal replacement product and investing in manufacturing operations, including personnel additions. The Company expects to continue to expand Apligraf manufacturing operations and to advance the Company's product pipeline during the next 12 months.

General and administrative expenses increased to \$1,521,000 and \$3,933,000 for the three and nine months ended September 30, 1998, compared to \$895,000 and \$2,800,000, for the same periods in 1997. The increase was primarily due to adding support staff and higher consulting and outside professional services, primarily relating to investor and public relations activities.

As a result of the net effect described, the Company incurred a net loss of \$5,690,000, or \$.19 per share, basic and diluted, and a net loss of \$8,242,000, or \$.28 per share, basic and diluted, for the three and nine months ended September 30, 1998, respectively, compared to a net loss of \$4,453,000, or \$.16 per share, basic and diluted, and \$15,113,000, or \$.54 per share, basic and diluted, for the comparable 1997 periods. The comparable 1997 period included a \$5,555,000 non-cash charge. The Company expects to incur additional losses in 1998 as its expenditures increase due to continued expansion of its operations and research programs.

Liquidity and Capital Resources:

From inception, the Company has financed its operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments and, to a lesser extent, sale of products and receipt of royalties. During the nine months ended September 30, 1998, financing activities provided additional cash and working capital to the Company from: the sale of 200 shares of Series C convertible preferred stock that generated net proceeds of approximately \$19,117,000; equity investments totaling \$6,000,000 from Novartis; and the exercise of stock options of \$981,000, partially offset by the purchase of treasury stock totaling \$247,000. Financing activities provided cash of approximately \$6,478,000 during the nine months ended September 30, 1997, from the exercise of stock options and warrants.

At September 30, 1998, the Company had cash, cash equivalents and investments in the aggregate amount of \$23,784,000 and working capital of \$22,509,000, compared to \$6,145,000 and \$4,843,000, respectively, at December 31, 1997. Cash used in operating activities during the nine months ended September 30, 1998 was \$7,220,000, compared to \$11,109,000 for the nine months ended September 30, 1997, primarily due to financing the Company's research, development and manufacturing operations. The Company expects operating expenditures to increase for the remainder of 1998 and into 1999 due to the expansion of Apligraf operations and for the advancement of the Company's product pipeline.

Capital expenditures were \$992,000 and \$826,000 during the nine months ended September 30, 1998 and 1997, respectively, primarily related to further build-out of the current facilities to support Apligraf manufacturing and the acquisition of laboratory equipment for expanded research and development and quality programs. The Company plans to spend an estimated \$6,000,000 over the next twelve months to modify its current facility in the areas of Apligraf manufacturing, quality labs and packaging. In addition, the Company plans to add a second facility to enable further expansion of manufacturing capacity.

Novartis has agreed to provide the Company up to \$40,000,000 in equity investments, research support and milestone payments (See "Collaborative Agreement" under the Notes to Consolidated Financial Statements), of which \$12,750,000 was received during 1998, \$2,500,000 in 1997 and \$11,500,000 in 1996. The remaining payments will be received based upon achievement of specified events. Under the agreement, the Company supplies Novartis' global requirements for Apligraf and receives revenue based on a per unit manufacturing payment and royalty on product sales.

Based upon its current plans, the Company believes that existing working capital together with future funds from Novartis, including product and royalty revenue, will be sufficient to finance its operations in 1999. However, the Company's manufacturing operations and research, clinical and capital expansion programs will require additional financial resources. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to the Company, if at all. Factors that may change the Company's cash requirements include: time required to obtain regulatory approvals of the Company's products in different countries, if needed, and subsequent timing of product launches; commercial acceptance when product launches occur; progress of the Company's research and development programs; resources the Company devotes to self-funded projects, proprietary manufacturing methods and advanced technologies; and resources the Company devotes to outside research collaborations or projects.

Year 2000:

The Year 2000 issue ("Y2K") refers to potential problems with computer systems or any equipment with computer chips or software that use dates where the date has been stored as just two digits (e. g., 98 for 1998). On January 1, 2000, any clock or date recording mechanism incorporating date sensitive software which uses two digits to represent the year may recognize a date using 00 as the year 1900 rather than the year 2000. This could result in a system failure or miscalculations causing disruption of operations, including, among other things, a temporary inability to process transactions, send invoices or engage in similar business activities.

In order to address this situation, the Company is conducting an assessment to identify and determine the Y2K readiness of the Company's systems. This assessment program focuses on three main functional areas, including: i) information technology which addresses data, phone and administrative systems; ii) embedded chip technology which addresses manufacturing systems, laboratory instruments and plant maintenance systems with programmable logic controllers with date functions; and iii) material suppliers, vendors, and other third parties which address areas that are critical to the Company's manufacturing process, distribution of product, or other business processes.

The task of assessment from a Y2K readiness perspective is in various stages of completion. Some of the Company's systems are Y2K compliant, whereas other systems have been identified as not being Y2K compliant and remedial action is underway. The assessment of the remaining software and systems to bring them into Y2K compliance in time to minimize any significant detrimental effects on operations is occurring currently. The Company expects to complete the assessment phase before the end of 1998 and that remedial plans will be in place shortly thereafter.

In addition to the assessment of systems, key vendors, suppliers and other third parties were identified and a survey form was sent to each of these business entities in order to determine if their systems are Y2K compliant. The Company is monitoring responses as they are received. Y2K issues with our vendors, suppliers or other third parties could be significant as delays in the shipment and receipt of critical supplies can impact the Company's production or the inability of customers to electronically order, store, or track product could impact operations. The Company is proactively addressing the Y2K issue with vendors, suppliers and other third parties in order to minimize risk from these external factors.

Although cost information is still being gathered, the Company currently estimates that the costs associated with the Year 2000 issue will not be material in relation to ongoing operations and working capital will be used to fund these costs. To date, these costs consist primarily of payroll costs for various employees, including the information technology group, which are not separately tracked. However, certain aspects of the Y2K assessment are still ongoing. If the Company or key third parties such as suppliers and customers are not Y2K ready, there could be an adverse effect on the Company's business, results of operations, and financial condition.

The Company believes that, with the implementation of its Y2K program, the risk of significant interruptions of normal operations is reduced. The Company is also developing a contingency plan to address a situation in which Year 2000 problems do cause an interruption in normal business activities. Once developed, contingency plans and related cost estimates will be continually refined as additional information becomes available.

Additional Cautionary Considerations:

The foregoing discussions that are not statements of current or historical fact are forward looking statements within the meaning of the Private Securities Litigation Reform act of 1995 and involve risks and uncertainties. In addition to the risks discussed above, the Company is subject to risks common to entities in the biotechnology industry, including, but not limited to, the following uncertainties: the Company's lead product, Apligraf, which was approved by the FDA on May 22, 1998 for the treatment of venous leg ulcers, will gain market acceptance in the United States; the Company's collaborative partner, Novartis, will be successful in marketing Apligraf for the treatment of venous leg ulcers in the United States and will be successful in additional registrations outside the United States; the Company will be able to manufacture in sufficient volume and sell its products to realize a satisfactory margin; continued availability of raw material for the Company's products; availability of sufficient product liability insurance; ability to recover the investment in property and equipment; risk of failure of clinical trials for future indications of Apligraf and other Company products; compliance with FDA regulations and similar foreign regulatory bodies; demand for the Company's products, if and when approved; protection of proprietary technology through patents; development by the Company's competitors of new technologies or products that are more effective than the Company's; dependence on and retention of key personnel; year 2000 issues; and availability of additional capital on acceptable terms, if at all.

## ORGANOGENESIS INC.

**PART II - OTHER INFORMATION****ITEM 5. OTHER INFORMATION**

Stockholders who wish to have their proposals presented at the 1999 Annual Meeting of Stockholders must deliver such proposals in writing to the Secretary of the Company at the principal executive office of Organogenesis in Canton, Massachusetts no later than December 4, 1998 for inclusion in the Company's proxy statement and form of proxy relating to that meeting. Stockholders who do not wish to include their proposals in such proxy statement and form of proxy but who wish to present proposals at the Company's 1999 Annual Meeting of Stockholders must notify the Secretary of the Company in writing at the Company's principal executive offices no later than February 19, 1999 in order for their proposals to be considered timely for purposes of Rule 14a-4 under the Securities Exchange Act of 1934, as amended.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

## (a) Exhibits

27 Financial Data Schedule (filed with electronic submission only)

(b) No current reports on Form 8-K were filed during the quarter ended September 30, 1998.

**ORGANOGENESIS INC.**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ORGANOGENESIS INC.**  
(Registrant)

Date: November 16, 1998

/s/ Herbert M. Stein

Herbert M. Stein, Chairman  
and Chief Executive Officer  
(Principal Executive Officer)

Date: November 16, 1998

/s/ Donna L. Abelli

Donna L. Abelli, Vice President Finance  
and Administration, Chief Financial  
Officer, Treasurer and Secretary  
(Principal Financial and Accounting  
Officer)

&lt;ARTICLE&gt; 5

&lt;LEGEND&gt;

**THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM FORM 10-Q AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.**

&lt;/LEGEND&gt;

&lt;MULTIPLIER&gt; 1,000

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